



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Infuse Bone Graft / LT Cage Lumbar Tapered Fusion
Docket Nos. 03E-0243 and 03E-0244

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

APR - 6 2004

Dear Acting Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,984,967 and 5,782,919 filed by SDGI Holdings, Inc. under 35 U.S.C. § 156. The medical device claimed by the patents is Infuse Bone Graft / LT Cage Lumbar Tapered Fusion, which was assigned PMA No. P000058.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on July 2, 2002, which makes the submissions of the patent term extension applications on August 30, 2002, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

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